



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,043	06/27/2003	Darin G. Schaeffer	10703/025	7932
27879	7590	06/30/2006	EXAMINER	
INDIANAPOLIS OFFICE 27879 BRINKS HOFER GILSON & LIONE ONE INDIANA SQUARE, SUITE 1600 INDIANAPOLIS, IN 46204-2033			HO, UYEN T	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,043	SCHAEFFER ET AL.	
	Examiner	Art Unit	
	(Jackie) Tan-Uyen T. Ho	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/08/03, 11/10/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The information disclosure statements (IDS) submitted on 11/10/03 and 12/08/03 are acknowledged and considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 29-30, 32, 33, 37-42, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Heck (6,083,207).

Heck discloses an introducer sheath having a sheath body (20) having a slit, an insertion member (16) having a handle (212) having C-shaped facing toward the distal tip of the sheath (also see fig. 3 of 5,098,392) or a handle (16) having a c-shape, a circumferential opening (34, fig. 3 of 5,098,392) or a circumferential opening form between to openings (34, 36), ring members (18), a homeostatic valve member (12), the handle having a pivotable portion and a disengageable portion (fig. 1 and 2), a dilator (300).

Art Unit: 3731

4. Claims 1, 6, 7, 11, 12, 29-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilson (6,514,280). Gilson disclose a delivery catheter comprising expandable sheath (3), an insertion cannula (2), a release mechanism (pushing the sheath out from the cannula), and a handle engaged with the sheath body (a handle inherently attached to sheath 3 and cannula 2 for pushing an withdrawing the sheath from the insertion cannula). Note: the claim language does not require the handle engaged directly to the sheath body.

5. Claims 1, 6, 7, 11, 12, 29-31, 46-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Laakso et al. (6,902,575). Laakso et al. disclose an expandable sheath (208), an insert cannula (203), a release mechanism comprising a pusher and handles (6, 2). The steps as claimed are inherently carried out as the Laakso et al.'s device being used.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-6, 8-10, 13-28, 34-36, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heck (6,083,207).

Regarding to the material of the sheath, Heck discloses all the limitations of the claims except fails to mention about the material of the sheath body as claimed. The

material of an introducer as claimed are well known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the introducer sheath of Heck reference from the claimed material in order to ease the advancement of an article inserted there through.

Regarding to the method steps as claimed, although, Heck does not clearly disclose step by step as claimed, Heck discloses an apparatus for use to delivering articles in a body opening and the apparatus including elements that carry out the steps as claimed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Heck's apparatus for delivering an article into a body opening. Doing so would carry out all the steps as claimed.

8. Claims 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laakso et al. '575 in view of Heck '207. Laakso et al. disclose all the limitations of the claims except for a presence of the handle as claimed. Heck discloses a delivery/introducer system comprising a handle as claimed in order to provide hemostasis valve system for introducing article into a body lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a handle as disclose by Heck into Laakso et al. in order to provide a hemostasis valve system and enhance the introduction of Laasko et al.'s apparatus into body lumen such handle having valve and adapted to couple and decouple from the introducer sheath.

Art Unit: 3731

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



(Jackie) Tan-Uyen T. Ho
Primary Examiner
Art Unit 3731

June 23, 2006